IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC, Plaintiffs, v. BARR LABORATORIES, INC., Defendant.	)	C.A. No. 06-286-GMS

REPLY TO DEFENDANT BARR LABORATORIES, INC'S COUNTERCLAIMS

Plaintiffs/Counterdefendants Aventis Pharmaceuticals Inc. ("Aventis") and Sanofi-Aventis US LLC (collectively, "Counterclaim Defendants"), by their undersigned attorneys, reply to the Counterclaims of Defendant/Counterplaintiff Barr Laboratories, Inc. ("Barr") as follows:

COUNTERCLAIM:

1. On information and belief, Aventis is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 1 of the counterclaims.

COUNTERCLAIM:

2. Barr is a wholly-owned subsidiary of Barr Pharmaceuticals, Inc, and is organized and existing under the laws of the State of Delaware, having its principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, New York 10970.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 2 of the counterclaims.

COUNTERCLAIM:

3. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*. as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

ANSWER: Paragraph 3 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants state that the FFDCA is a statute, and does not set forth "rules," and therefore deny the allegations contained in paragraph 3 of the counterclaims.

COUNTERCLAIM:

4. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

ANSWER: Paragraph 4 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 4 of the counterclaims.

COUNTERCLAIM:

5. A NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

ANSWER: Paragraph 5 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants deny the allegations contained in paragraph 5 of the counterclaims.

COUNTERCLAIM:

6. Upon approval of the NDA, FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

ANSWER: Paragraph 6 of the counterclaims states legal conclusions to which no

response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 6 of the counterclaims.

COUNTERCLAIM:

7. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original.

ANSWER: Counterclaim Defendants admit that the allegations contained in paragraph 7 of the counterclaims are generally true, but deny that they are always true.

COUNTERCLAIM:

8. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

ANSWER: Paragraph 8 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 8 of the counterclaims, except to the extent that they allege or imply that Congress enacted the Hatch-Waxman amendments for a single purpose or that generic manufacturers always must file an ANDA.

COUNTERCLAIM:

9. To receive approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

ANSWER: Paragraph 9 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants

admit the allegations contained in paragraph 9 of the counterclaims.

COUNTERCLAIM:

10. An ANDA also must contain a "certification" to each patent that the NDA holder has submitted to FDA for listing in the Orange Book in connection with the listed reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(.vii.); 21 C.F.R. § 314.94(a)(12).

ANSWER: Paragraph 10 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 10 of the counterclaims.

COUNTERCLAIM:

11. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12).

ANSWER: Paragraph 11 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 11 of the counterclaims.

COUNTERCLAIM:

12. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

ANSWER: Paragraph 12 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 12 of the counterclaims.

COUNTERCLAIM:

13. Upon receiving notice of the paragraph IV certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 13 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 13 of the counterclaims.

COUNTERCLAIM:

14. Patent holders have a significant strategic incentive to file suit within 45 days because doing so, regardless of merit, prevents FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: Paragraph 14 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 14 of the counterclaims, except to the extent that they suggest that patent holders have any incentive to file suit regardless of merit.

COUNTERCLAIM:

15. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, FDA will not approve the ANDA until the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringe, FDA may approve the ANDA. *Id*.

ANSWER: Paragraph 15 of the counterclaims states legal conclusions to which no response is required. To the extent that a response is required, Counterclaim Defendants admit the allegations contained in paragraph 15 of the counterclaims.

COUNTERCLAIM:

16. Barr filed an ANDA (No. 78-104) with FDA seeking generic approval for triamcinolone acetonide aqueous nasal spray, 0.055 µg/spray. The ANDA shows that Barr's ANDA product is bioequivalent to the product that is the subject of NDA No. 20-468, the holder of which FDA lists as Sanofi-Aventis US LLC ("Sanofi-Aventis" and, together with Aventis, "Plaintiffs").

ANSWER: Counterclaim Defendants admit that Barr filed ANDA No. 78-104 with

the FDA seeking generic approval for triamcinolone acetonide aqueous nasal spray, 0.055 µg/spray. Counterclaim Defendants admit that Sanofi-Aventis is the holder of NDA 20-468, but otherwise lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 16 of the counterclaims, and therefore deny the same.

COUNTERCLAIM:

17. Sanofi-Aventis listed U.S. Patent Nos. 5,976,573 ("the '573 patent") and 6,143,329 ("the '329 patent") in the Orange Book in connection with NDA No. 20-468.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 17 of the counterclaims.

COUNTERCLAIM:

18. Because Barr seeks FDA approval to market its ANDA product before expiration of the '573 and '329 patents, Barr's ANDA includes paragraph IV certifications to those patents.

ANSWER: Counterclaim Defendants admit that the ‘573 and ‘329 patents have not expired, but otherwise lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 18 of the counterclaims, especially as they relate to Barr’s state of mind or motives, and therefore deny the same.

COUNTERCLAIM:

19. On March 20, 2006, Barr sent to Plaintiffs a statutorily-required notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to why the `573 and '329 patents are invalid, unenforceable, and/or not infringed by Barr's ANDA product.

ANSWER: Counterclaim Defendants admit that they received a paragraph IV certification from Barr dated March 20, 2006. Counterclaim Defendants deny the remaining allegations of paragraph 19 of the counterclaims.

COUNTERCLAIM:

20. On May 2, 2006, Plaintiffs filed their patent infringement lawsuit against Barr, alleging that Barr's ANDA product would infringe the '573 and '329 patents.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 20 of the counterclaims.

COUNTERCLAIM:

21. Barr realleges and incorporates by reference the allegations of paragraphs 1-20.

ANSWER: Counterclaim Defendants repeat and reassert their responses to the allegations contained in paragraphs 1-20 of the counterclaims.

COUNTERCLAIM:

22. Present, genuine and justiciable controversies exist between Aventis and Barr regarding the '573 and '329 patents.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 22 of the counterclaims, to the extent that such controversies are limited to Barr's ANDA filing.

COUNTERCLAIM:

23. Subject matter jurisdiction over these counterclaims exists under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Counterclaim Defendants admit that this Court has subject matter jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) to the extent that it purports to state a claim based solely on the ANDA filing. Counterclaim Defendants deny the remaining allegations contained in paragraph 23 of the counterclaims.

COUNTERCLAIM:

24. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 24 of the counterclaims.

COUNTERCLAIM:

25. Barr realleges and incorporates by reference the allegations of paragraphs 1-24.

ANSWER: Counterclaim Defendants repeat and reassert their responses to the allegations contained in paragraphs 1-24 of the counterclaims.

COUNTERCLAIM:

26. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. *§* 1 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '573 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

ANSWER: Counterclaim Defendants admit that this counterclaim purports to arise under 35 U.S.C. § 1 et seq. and 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '573 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112. Counterclaim Defendants deny the remaining allegations contained in paragraph 26 of the counterclaims.

COUNTERCLAIM:

27. A present, genuine, and justiciable controversy exists between Aventis and Barr regarding, *inter alia*, the validity of claims of the '573 patent.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 27 of the counterclaims to the extent that the controversy is limited to Barr's ANDA filing.

COUNTERCLAIM:

28. Claims of the '573 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

ANSWER: Counterclaim Defendants deny the allegations contained in paragraph 28 of the counterclaims.

COUNTERCLAIM:

29. Barr is entitled to a declaration that claims of the '573 patent are invalid.

ANSWER: Counterclaim Defendants deny the allegations contained in paragraph 29 of the counterclaims.

COUNTERCLAIM:

30. Barr realleges and incorporates by reference the allegations of paragraphs 1-29.

ANSWER: Counterclaim Defendants repeat and reassert their responses to the allegations contained in paragraphs 1-29 of the counterclaims.

COUNTERCLAIM:

31. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. *§* 1 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '573 patent will not be infringed by the manufacture, use, or sale of the products described in Barr's ANDA No. 78-104.

ANSWER: Counterclaim Defendants admit that this counterclaim purports to arise under 35 U.S.C. § 1 et seq. and 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '573 patent will not be infringed by the manufacture, use, or sale of the products described in Barr's ANDA No. 78-104. Counterclaim Defendants deny the remaining allegations contained in paragraph 31 of the counterclaims.

COUNTERCLAIM:

32. A present, genuine, and justiciable controversy exists between Aventis and Barr regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Ban's proposed ANDA product would infringe claims of the '573 patent.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 32 of the counterclaims to the extent that the controversy is limited to Barr's ANDA filing. Counterclaim Defendants deny the allegations of paragraph 32 of the counterclaims to the

extent that they relate to the manufacture, use, or sale of the products described in Barr's ANDA No. 78-104.

COUNTERCLAIM:

33. The manufacture, use, or sale of Barr's ANDA products would not infringe claims of the '573 patent.

ANSWER: Counterclaim Defendants deny the allegations contained in paragraph 33 of the counterclaims.

COUNTERCLAIM:

34. Barr is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '573 patent.

ANSWER: Counterclaim Defendants deny the allegations contained in paragraph 34 of the counterclaims.

COUNTERCLAIM:

35. Barr realleges and incorporates by reference the allegations of paragraphs 1-34.

ANSWER: Counterclaim Defendants repeat and reassert their responses to the allegations contained in paragraphs 1-34 of the counterclaims.

COUNTERCLAIM:

36. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. *§* 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '329 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

ANSWER: Counterclaim Defendants admit that this counterclaim purports to arise under 35 U.S.C. § 1 et seq. and 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '329 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112. Counterclaim Defendants deny the remaining allegations

contained in paragraph 36 of the counterclaims.

COUNTERCLAIM:

37. A present, genuine, and justiciable controversy exists between Aventis and Barr regarding, *inter alia*, the validity of claims of the '329 patent.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 37 of the counterclaims to the extent that the controversy is limited to Barr's ANDA filing.

COUNTERCLAIM:

38. Claims of the '329 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

ANSWER: Counterclaim Defendants deny the allegations contained in paragraph 38 of the counterclaims.

COUNTERCLAIM:

39. Barr is entitled to a declaration that claims of the '329 patent are invalid.

ANSWER: Counterclaim Defendants deny the allegations contained in paragraph 39 of the counterclaims.

COUNTERCLAIM:

40. Barr realleges and incorporates by reference the allegations of paragraphs 1-39.

ANSWER: Counterclaim Defendants repeat and reassert their responses to the allegations contained in paragraphs 1-39 of the counterclaims.

COUNTERCLAIM:

41. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. *§* 1 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '329 patent will not be infringed by the manufacture, use, or sale of the products described in Barr's ANDA No. 78-104.

ANSWER: Counterclaim Defendants admit that this counterclaim purports to arise

under 35 U.S.C. § 1 et seq. and 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the ‘329 patent will not be infringed by the manufacture, use, or sale of the products described in Barr’s ANDA No. 78-104. Counterclaim Defendants deny the remaining allegations contained in paragraph 41 of the counterclaims.

COUNTERCLAIM:

42. A present, genuine, and justiciable controversy exists between Aventis and Barr regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Barr's proposed ANDA product would infringe claims of the '329 patent.

ANSWER: Counterclaim Defendants admit the allegations contained in paragraph 42 of the counterclaims to the extent that the controversy is limited to Barr’s ANDA filing. Counterclaim Defendants deny the allegations of paragraph 42 of the counterclaims to the extent that they relate to the manufacture, use, or sale of the products described in Barr’s ANDA No. 78-104.

COUNTERCLAIM:

43. The manufacture, use, or sale of Barr's ANDA products would not infringe claims of the '329 patent.

ANSWER: Counterclaim Defendants deny the allegations contained in paragraph 43 of the counterclaims.

COUNTERCLAIM:

44. Barr is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '329 patent.

ANSWER: Counterclaim Defendants deny the allegations contained in paragraph 44 of the counterclaims.

ADDITIONAL RESPONSE TO COUNTERCLAIMS:

Counterclaim defendants contend that Barr's jury demand on declaratory judgment counterclaims is inappropriate in an ANDA action as a matter of law, and that this issue is best resolved via motion under Rule 39 at a time to be determined by the Court. Counterclaim defendants do not believe that a jury demand objection can be waived by not raising the issue in their responsive pleading. However, out of an abundance of caution, counterclaim defendants hereby provide Barr with notice of their intent to seek resolution of this issue at a time of the Court's choosing.

ASHBY & GEDDES

/s/ *John G. Day*

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Dated: June 9, 2006
170309.1

CERTIFICATE OF SERVICE

I hereby certify that on the 9th day of June, 2006, the attached **REPLY TO DEFENDANT BARR LABORATORIES, INC'S COUNTERCLAIMS** was served upon the below-named counsel of record at the address and in the manner indicated:

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